UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BART MASSARO :

:

v. : JURY TRIAL DEMANDED

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NO. 02-CV-2678

BARD ACCESS SYSTEMS, INC.

ANSWER OF DEFENDANT, BARD ACCESS SYSTEMS, INC., TO PLAINTIFF'S COMPLAINT WITH AFFIRMATIVE DEFENSES

Defendant, Bard Access Systems, Inc. (hereinafter "Bard"), by and through its attorneys, Rawle & Henderson, LLP, hereby answers plaintiff's Complaint and sets forth affirmative defenses as follows:

FIRST DEFENSE

Plaintiff's complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

Plaintiff's complaint fails to state a cause of action against the defendant, Bard Access Systems, Inc.

THIRD DEFENSE

Answering defendant responds to the individual allegations of plaintiff's complaint as follows:

1. Admitted in part, denied in part. It is admitted that plaintiff is a resident of Pennsylvania. As to the allegation regarding plaintiff's exact age, answering defendant is without knowledge or information sufficient to form a belief as to the truth of that allegation and,

accordingly, answering defendant denies that allegation and demands proof thereof at the time of trial, if relevant.

- 2. The allegations contained in paragraph 2 are denied as stated. Bard Access Systems, Inc. is a corporation incorporated in the State of Utah with a principal place of business located in Salt Lake City, Utah.
- 3. In response to the allegations contained in paragraph 3, it is admitted that answering defendant has conducted business in the State of Pennsylvania. To the extent it is alleged that answering defendant "had substantial contacts with and/or regularly conducted business in Philadelphia, Pennsylvania," those allegations constitute conclusions of law and they are, therefore, deemed denied.
- 4. In response to the allegations contained in paragraph 4, it is denied that answering defendant designed or manufactured a peripherally inserted central catheter (hereinafter "PICC"). Answering defendant is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 4 and, accordingly, answering defendant denies those allegations and demands proof thereof.
- 5-7. The allegations contained in paragraphs 5-7 of the plaintiff's complaint constitute conclusions of law and they are, therefore, deemed denied.
- 8-28. Answering defendant is without knowledge or information sufficient to form a belief as to the truth of the factual allegations contained in paragraphs 8-28 of plaintiff's complaint and, accordingly, answering defendant denies those allegations and demands proof thereof.
- 29-30. Defendant denies that plaintiff was injured by any defect in any product manufactured, designed or supplied by the answering defendant. Furthermore, the allegations

contained in paragraphs 29 and 30 of plaintiff's complaint constitute conclusions of law and they are, therefore, deemed denied.

- 31. The allegations contained in paragraph 31 (a)-(j) constitute conclusions of law and they are, therefore, deemed denied. By way of further answer, after reasonable investigation, answering defendant is without knowledge or information sufficient to admit or deny plaintiff's allegations of injury and damages. Answering defendant specifically denies, however, that any injury alleged by the plaintiff was caused by the answering defendant, its agents, servants, or employees.
- 32. In response to the allegations contained in paragraph 32, answering defendant incorporates by reference its answers and responses to all other paragraphs contained in plaintiff's complaint as if fully set for forth herein at length.
 - 33. The allegations contained in paragraph 33 (a)-(f) are denied.
- 34. In response to the allegations contained in paragraph 34, answering defendant incorporates by reference its answers and responses to all other paragraphs contained in the plaintiff's complaint as if fully set forth at length herein.
 - 35-39. The allegations in paragraphs 35-39 of plaintiff's complaint are denied.
- 40. In response to the allegations contained in paragraph 40, answering defendant incorporates by reference its answers and responses to all other paragraphs contained in plaintiff's complaint as if fully set forth at length herein.
- 41-44. The allegations contained in paragraphs 41-44 of plaintiff's complaint constitute conclusions of law and they are, therefore, deemed to be denied. To the extent that these corresponding paragraphs contain factual allegations, the same are also denied.

FOURTH DEFENSE

The claims for relief set forth in the plaintiff's complaint are barred and/or limited in accordance with the doctrine of contributory regligence and/or in accordance with the doctrine of comparative negligence because the negligence of the plaintiff caused and/or contributed to the causing of his alleged injuries.

FIFTH DEFENSE

Answering defendant neither made nor breached any express or implied warranties which were, in any way, responsible for plaintiff's alleged damages.

SIXTH DEFENSE

Any claims of plaintiff based upon an alleged breach of warranty, expressed or implied, are barred by law because there was and is not privity of contract between the plaintiff and the answering defendant and because plaintiff failed to provide the answering defendant with timely notice of any alleged breach of warranty.

SEVENTH DEFENSE

The injuries and damages allegedly sustained by plaintiff were caused solely or in part by a person or persons over whom answering defendant had no control, and/or no right to control, thus barring recovery from answering defendant in whole or in part.

EIGHTH DEFENSE

The injuries and damages allegedly sustained by plaintiff were caused by an intervening cause and/or superseding cause and, therefore, the plaintiff may not recover against answering defendant.

NINTH DEFENSE

The injuries and damages allegedly sustained by plaintiff were caused by the intervening actions and/or omissions of a third party or parties for whom answering defendant is not responsible and, therefore, the plaintiff may not recover against the answering defendant.

TENTH DEFENSE

The plaintiff's injuries, if any, were the result of pre-existing or subsequent conditions which are unrelated to any product that the answering defendant may have designed, manufactured, sold or distributed.

ELEVENTH DEFENSE

Upon information and belief, the plaintiff had full knowledge of the risk and possible adverse effects arising from the use of the subject product, and all or part of the injuries, damages and/or losses, if any, sustained by the plaintiff arose from or were caused by such risks, and such risks were accepted and assumed by the plaintiff, and for that reason, any recovery by the plaintiff is barred in accordance with the principals of the assumption of the risk or informed consent.

TWELFTH DEFENSE

The injuries and damages allegedly sustained by the plaintiff were caused by the unforeseeable alteration, misuse, abuse and/or improper use or handling of the product referred to in plaintiff's complaint.

THIRTEENTH DEFENSE

Plaintiff's state law claims are barred to the extent that they are preempted by Federal statutory, regulatory or decisional law. The peripherally inserted central catheter line of which plaintiff complains is a medical device subject to regulation under the Medical Devices Amendments Act of 1976 to the Federal Food, Drug and Cosmetic Act and all claims under state law are therefore subject to the Doctrine of Federal Preemption.

FOURTEENTH DEFENSE

Answering defendant is entitled to a set off or credit in the amount of any settlement or compromise heretofore or hereafter reached by the plaintiff with any other person for any of plaintiff's alleged damages.

FIFTEENTH DEFENSE

Answering defendant avers that if it provided any product which is the subject of this lawsuit, such product was sold and/or distributed in accordance with any and all governmental and administrative regulations and standards.

SIXTEENTH DEFENSE

Plaintiff's claim for damages must be dismissed or reduced to the extent that he has failed to mitigate his damages.

SEVENTEENTH DEFENSE

Plaintiff has failed to plead product identification with particularity.

EIGHTEENTH DEFENSE

The benefits of the product at issue outweigh the risks, if any, which may be attendant to its use and public policy dictates against holding answering defendant responsible for any alleged injuries suffered by the plaintiff, on any theory of strict liability.

NINETEENTH DEFENSE

If plaintiff suffered injuries which were caused by the products at issue, that product was "unavoidably unsafe" as discussed in comment K to the Restatement (2nd) of Torts, Section 402a.1

TWENTIETH DEFENSE

If the plaintiff suffered injuries as alleged, said injuries were the result of an idiosyncratic and/or allergic reaction.

WHEREFORE, defendant, Bard Access Systems, Inc., denies that it is liable to the plaintiff for any sum or sums whatsoever and demands judgment in its favor.

RAWLE & HENDERSON LLP

By: Thomas P. Wagner, Esquire Mary Peraria, Esquire Attorneys for Defendant Bard Access Systems, Inc.

Comment k, which is entitled "Unavoidably unsafe products," denies application of strict liability to products such as prescription drugs and certain medical devices, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings.

The Widener Building One South Penn Square Philadelphia, PA 19107 (215) 575-4200

Dated:

CERTIFICATE OF SERVICE

I do hereby certify that a true and correct copy of the foregoing Answer of Defendant, Bard Access Systems, Inc., to Plaintiff's Complaint with Affirmative Defenses was sent by First Class mail, postage prepaid, to the following counsel of record and unrepresented parties:

> Michael Smerconish, Esquire Beasley, Casey & Erbstein 1125 Walnut Street Philadelphia, PA 19107-4997

> > By: Thomas P. Wagner, Esquire Mary Peraria, Esquire Attorneys for Defendant, Bard Access Systems, Inc.

Date: